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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,142	11/09/2000	Alessandra Pavesio	515-4210	1911

7590

07/01/2003

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EXAMINER

JONES, DWAYNE C

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 07/01/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

09/700,142

Applicant(s)

PAVESIO ET AL.

Examiner

Dwayne C Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 Feb 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Status of Claims

1. Claims 36-45 are pending.
2. Claims 36-45 are rejected.
3. Claims 1 and 24-35 were cancelled as per the amendment of February 13, 2003.

Response to Arguments

4. Applicant's arguments filed February 13, 2003 have been fully considered but they are not persuasive. Applicants make the following unpersuasive arguments. First, applicants allege that Dorigatti et al. is directed to total esters or partial esters of HA that have a degree of esterification that is higher than 85%. In fact, applicants intimate that Examples 1, 7 and 15 are only for the preparation of the esters of HA, whereas the non-woven biomaterials of Dorigatti et al. are described in Examples 27-31.

5. Applicants allege that Dorigatti et al. is directed to total esters or partial esters of HA that have a degree of esterification that is higher than 85%. Example 1 clearly teaches of generating a partial ester of HA that has 50% of the carboxylic groups esterified and 50% and 50% of the carboxylic acid groups have undergone salification with a metal, (see from page 20, line 30 to page 21, line 20). In fact, Dorigatti et al. specifically teach that, "[i]n the esters obtained according to this procedure or according to the other procedure described hereafter, free carboxylic groups of the partial esters may be salified, if desired". (as cited from page 18, lines 24-27). In addition, Dorigatti et al. state that, "[i]n the partial esters it is possible to salify all the remaining carboxylic

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groups or only part of them", (see page 21, lines 2 and 3). Upon reviewing the Dorigatti et al. specification the skilled artisan is clearly provided with the motivation and guidance to make both partial esters of HA and even full esters of HA (specifically 100 % of the carboxylic acid groups are esterified). After generating these partial esters of HA as taught by Dorigatti et al., the skilled artisan is clearly provided with the motivation and direction to make biocompatible non-woven fabric biomolecules that are for use in surgery and specifically for the regeneration of tissues. Regarding applicants' allegation that Examples 27-31 are directed to the non-woven biomaterials, it is noted that Examples 27-31 are in fact, just examples to teach and shown the skilled artisan how to make biocompatible non-woven fabric biomolecules with both the full and partial esters as clearly taught by Dorigatti et al. In addition, Examples 28 and 29 are specifically is directed to a making membranes comprised of a matrix of "a partial benzyl ester (75%) of hyaluronic acid". Furthermore, it noted that claim 20 states that, "[t]he composite membrane of claim 19, wherein said fibers are present in equal amounts, and wherein said partial benzyl ester of hyaluronic acid is a 75% benzyl ester of hyaluronic acid". For these reasons, the instant claims are rejected over the prior art reference of Dorigatti et al.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. The rejection of claims 36-42 under 35 U.S.C. 103(a) as being unpatentable over

Dorigatti et al. of WO 93/11803 is maintained and repeated. Dorigatti et al. teach of biocompatible non-woven fabric biomaterials for use in surgery and specifically for the regeneration of tissues. In addition, Dorigatti et al. teach that these biomaterials are comprised of esters of hyaluronic acid with aliphatic, araliphatic, cycloaliphatic, or heterocyclic alcohols, (see pages 7 and 8). Furthermore, Dorigatti et al. disclose that this biomaterial of the partial esters of hyaluronic acid ester have less than 85% of the groups esterified. In fact, Dorigatti et al. teach that 50% of the carboxylic acid groups are esterified in Example 1, (see pages 18-19) and 75% of the carboxylic acid groups are esterified in Example 7, (see page 24) and that 85% of the carboxylic acid groups are esterified in Example 15, (see pages 27-28). In addition, the prior art reference of Dorigatti et al. do not claim nor teach of the incorporation of cellular components, (see claims 1-29). Dorigatti et al. also teach of the benzyl esters of hyaluronic acid in Example 12, (see page 26). Dorigatti et al. also teach that the useful esters include

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esters which derive from alcohols which themselves possess a notable pharmacological action, (see page 11, lines 4-9 and from page 11, line 30 to page 17, line 17).

Furthermore, this prior art invention is directed to use in a variety of surgical procedures, namely orthopedics, (see pages 39 and 40). Even though Dorigatti et al. do not specifically teach of excluding cellular components and products in these biomaterials of hyaluronic acid ester, it is noted that Dorigatti et al. do not teach in this patent of including cellular components and products in this biomaterial of esters of hyaluronic acid. Clearly, it would have been obvious to one having ordinary skill in the art at the time of the invention to utilize the teachings of Dorigatti et al. to arrive at the instant invention because Dorigatti et al. do not disclose of including cellular components and products in this biomaterial of esters of hyaluronic acid.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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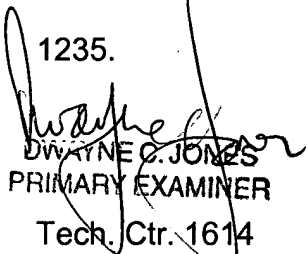
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1235.


DWAYNE C. JONES
PRIMARY EXAMINER

Tech. Ctr. 1614
June 27, 2003